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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,407	12/26/2001	Larry Caldwell	TOPI-002CIP	3764
24353 7590 02/26/2007 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/029,407	Applicant(s) CALDWELL ET AL.	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-28 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged applicants' amendment and request declarations filed 06/26/2006.

Claims 1-26 previously presented, and claims 27 and 28 have been added.

Claims 1-28 are pending and included in the prosecution.

Inventorship

1. In view of the papers filed 06/26/2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(c). The inventorship of this application has been changed by addition of Lawrence Newman as an inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

The following rejections have been overcome by virtue of applicants' amendment, declaration, and remarks:

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- (A) The rejection of claims 1-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.
- (B) The rejection of claims 1, 2, 5-7, 10, 11, 24-26 under 35 U.S.C. 102(e) as being anticipated by US 6,416,772 ('772).
- (C) The rejection of claims 1-13, 16, 19-26 under 35 U.S.C. 102(e) as being anticipated by US 2002/0143047 ('047).
- (D) The rejection of claims 1, 2, 5-7, 10, 11, 14-18, and 24-26 under 35 U.S.C. 103(a) as being unpatentable over US 6,416,772 ('772) combined with US 5,318,960 ('960).
- (E) The rejection of claims 1-26 under 35 U.S.C. 103(a) as being unpatentable over US 6,416,772 ('772) combined with US 5,725,874 ('874).

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,855,907 ('907) in view of the article "Indomethacin-responsive episodic cluster headache" by Geaney.

US '907 teaches method for treating migraine by topical administration of migraine ameliorating effective amount of opioid in combination with anti-inflammatory compounds including NSAID including indomethacin and ibuprofen that can be administered sequentially from the opioid (col.5, lines 55-67; col.6, lines 20-22). The references disclosed topical formulations including gel, ointment, and the like, and transdermal formulations applied around the sinal cavity (col.4, lines 20-23; col.5, lines 2-4).

Although US '907 suggested NSAID administered sequentially from opioid, i.e. by itself, however, US '907 does not specifically teach indomethacin by as the only active ingredient. US '907 does not teach ketoprofen in particular as NSAID as claimed in claim 18, or the kit including instruction as claimed in claims 19-23.

The art recognized the suitability of NSAID to treat migraine and this should include all the NSAID. In absence of showing superior and unexpected results obtained from using ketoprofen, claim 18 is unpatentable over the prior art.

Regarding the kit including written instruction to the consumer, the written instruction does not make the claims patentable. See *In re Ngai* 03-1524.

The article by Geaney teaches indomethacin can dramatically abolish cluster headache (see the provided abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat migraine by using indomethacin sequentially with opioid topically at the sinal cavity area as disclosed by US '907, and rely on indomethacin alone to treat migraine as disclosed by Geaney, motivated by the teaching of Geaney that indomethacin can dramatically abolish cluster headache, with reasonable expectation of treating migraine successfully by topical application of indomethacin.

5. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Migraine Headaches" in view of the article "Indomethacin-responsive episodic cluster headache" by Geaney.

The article "Migraine Headaches" teaches treating migraine by rubbing herbal medicinal formulation containing herbs known to treat migraine into the forehead and temples of the patients (see the entire document).

However, the article does not teach NSAID to treat migraine, or the kit with instruction as claimed in claims 19-23.

The kit including written instruction to the consumer does not make the claims patentable. See *In re Ngai 03-1524*.

The article by Geaney teaches indomethacin can dramatically abolish cluster headache (see the provided abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat migraine by using topical medicine known to treat migraine rubbed into the forehead or temples of the patient as disclosed by the article "Migraine Headaches", and use indomethacin to treat migraine instead of herbal medicine as disclosed by Geaney, motivated by the teaching of Geaney that indomethacin can dramatically abolish cluster headache, with reasonable expectation of treating migraine successfully by topical application of indomethacin to the patient's temples or forehead.

The combination of the references does not teach the specific NSAID as claimed in claims 17 and 18. The art recognized the suitability of NSAID to treat migraine and this should include all the NSAID. In absence of showing superior and unexpected results obtained from using ibuprofen or ketoprofen, claims 17 and 18 are unpatentable over the prior art.

Response to Arguments

6. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

7. The declaration under 37 CFR 1.132 filed 01/05/2006 has been considered but is moot in view of the new ground(s) of rejection. The newly recited prior art showed that migraine that is centrally originated headache can be treated with topical formulations.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,139,861 disclosed treatment of migraine by applying to the mucous membrane of the mouth NSAID including ibuprofen and ketoprofen.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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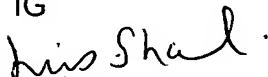
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

IG



ISIS GHALI
PRIMARY EXAMINER